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The Fortification of Foods: A Review

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This handbook discusses fortification of foods from 1924-80.

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SUMMARY

This handbook provides background information on the history, current practices, and technological aspects of food fortification. It also describes fortification programs in other countries.

History--Food fortification programs in the United States started as a means of correcting serious nutritional deficiencies in some portions of the population. Addition of iodine to salt to help prevent goiter, vitamin D to milk to help prevent rickets, and niacin to bread to help prevent pellagra are the best known examples of health related fortification practices. Enrichment of bread with iron, thiamin, and riboflavin as well as niacin, and required fortification of oleomargarine with vitamin A are practices which grew out of health problems identified during World War II.

Technology of fortification-Technological problems in developing effective fortification procedures include identifying biologically available forms of a nutrient and factors affecting bioavailability, developing knowledge of maximum safe intake levels for nutrients, determining the stability of added nutrients during storage and processing, determining the most suitable carrier food for the fortifying nutrients, and determining what changes the added nutrients would cause in the carrier food.

Current Practices--Various foods are fortified. Examples include cereals, flour, baked goods, beverages, milk, infant formulas, margarine, and meal replacements. However, it is difficult to determine the relative effectiveness of fortification, compared with the effects of an improved economy in improving nutritional status.

Current Practices--Various foods are fortified. Examples include cereals, flour, baked goods, beverages, milk, infant formulas, margarine, and meal replacements. However, it is difficult to determine the relative effectiveness of fortification, compared with the effects of an improved economy in improving nutritional status.

The Food and Drug Administration (FDA) has established standards for the amounts of nutrients to be added when bread, flour, or dairy products are fortified, but does not require any products to be fortified. States set their own requirements for which foods should be fortified, and tend to follow FDA standards.

In January 1980, the FDA published a policy statement giving guidelines for fortification of foods. The guidelines were based primarily on recommendations that had been published by the Food and Nutrition Board of the National Academy of Sciences and the Council on Foods and Nutrition of the American Medical Association. The FDA's policy statement includes guidelines: 1) for determining when fortification is desirable, 2) for selecting foods to be fortified, 3) for restoring nutrients lost in processing, 4) for determining the amounts of nutrients to use in fortifying foods, 5) on the desirability of fortifying substitute foods to make them nutritionally comparable to the traditional food, 6) on the need for nutrients used in fortification to be stable and physiologically available, and 7) on the need for label claims for fortified foods not to be false or misleading. The Food and Nutrition Service of the U.S. Department of Agriculture (USDA) has developed policies requiring fortification with iron and selected vitamins of certain foods--milk, infant formula, cereal, and

juices--used in the Women, Infants, and Children (WIC) program. Foods purchased by USDA for use in the School Lunch and Needy Family programs, with few exceptions, may be fortified only if FDA has a standard for the product, such as enriched bread and flour. The Food Safety and Inspection Service maintains the policy of not allowing direct fortification of meat and poultry but does allow fortified ingredients, such as enriched flour or fortified textured vegetable protein, to be used in meat and poultry products. FDA guidelines are followed for these fortified ingredients.

INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture has responsibility under the Federal Meat Inspection Act (1) and the Poultry Products Inspection Act (2) for ensuring that meat and poultry products in the market are wholesome, unadulterated, and properly labeled.1/

These activities are carried out by in-plant inspection of slaughter and processing procedures; and by establishment of food standards, labeling requirements, and use limits for ingredients in products. The Department of Agriculture also must approve product labels before meat and poultry products can be marketed in interstate commerce. Scientific services--including chemical, pathological, and microbiological evaluations; monitoring of residues; and compliance and sanitation reviews--provide necessary support to the inspection activities. Policy reviews are made as needed to determine whether changing conditions in food technology or consumer needs or new knowledge of nutrition, health, or food safety indicate that changes in FSIS procedures or policy would be useful.

Presently, there is particular concern among nutritionists with the apparent decreasing intake in quantity of foods which has followed decreasing energy expenditures by many Americans. This lowering in quantity of food consumed has been observed by comparisons of data from the USDA Individual Food Consumption Surveys for 1965-66 and 1977-78 (3). When individuals decrease the quantity of food they consume, their requirements for most essential nutrients do not decrease in a like manner. Therefore, it becomes important to increase the nutrient density, or nutrients per unit of food energy (calories) consumed. Fortification of foods is one means of increasing nutrient density.

Health specialists frequently view food fortification with mixed feelings. It is generally recognized that food fortification programs have assisted in virtually eliminating pellagra, beriberi, ariboflavinosus, rickets, and goiter from the United States through addition of key nutrients to foods such as flour and bread--items that are economically priced and widely consumed by a large segment of the population. However, there is concern that addition of nutrients to foods that are inherently low in nutritive value, such as soft drinks, could encourage the selection of these foods, rather than similar but more nutritious foods such as fruit juices. Nutritional "horsepower" races, that is, the addition of increasing numbers and amounts of nutrients to meet or beat market competition, could result in overconsumption past safe limits of intakes.

This handbook was prepared to provide background information on the history, current practices, and technological aspects of food fortification. It is intended for use in any reviews of fortification policy that FSIS might make and to be a convenient summary of information for anyone needing information on fortification of foods.

1/ Italicized numbers in parentheses refer to items in the References.

DEFINITIONS OF TERMS

Many terms have been used to describe the addition of nutrients to foods. "Enrichment" or "enriched" is usually used to describe the addition of nutrients already present in a food. No new nutrients are added, but the levels of naturally occurring nutrients are enhanced, usually to meet a legal standard (4). An example of enrichment is the addition of thiamin, riboflavin, niacin, and iron to wheat flour. The terms "fortification" or "fortified" are used to describe the addition of nutrients not naturally present in a food, such as the addition of vitamin D to milk (4).

"Restoration" is a term used when naturally occurring nutrients lost in processing are added back to preprocessing levels (4). One example of restoration is the restoration of vitamin A to dried skim milk.

Many times the terms "enrichment" and "fortification" are used interchangeably. For the purpose of this report, "enrichment" will refer only to the standards of enrichment established by the Food and Drug Administration in published regulations. "Fortification" will refer to any kind of nutrient addition. This combining of definitions for "enrichment" and "fortification" follows FDA's 1980 final policy statement on fortification (5).

HISTORY OF POLICIES IN THE UNITED STATES

Nutrient additions to foods in the United States began in 1924 after research conducted in Michigan showed that sodium iodide is effective in preventing goiter (6). Goiter was a prevalent health problem at that time, but groups such as the American Public Health Association (APHA), the Council on Foods and Nutrition of the American Medical Association (AMA), and the Food and Nutrition Board of the National Research Council (NRC) were very cautious about recommending fortification of salt with iodine. Eventually their support was given, but fortification programs were kept voluntary to minimize the risk of overconsumption of iodine (6).

In 1933 the Council on Foods and Nutrition of the AMA began to recommend the fortification of milk with vitamin D (6). The relationship between vitamin D deficiency and the development of rickets (a disease in which the bones become deformed because of malabsorption of calcium) had been recognized at that time. Milk was selected as the carrier food for several reasons: 1) milk has a high content of calcium and phosphorus, minerals which are major components of bone; 2) vitamin D is directly concerned with the utilization of these minerals; and 3) milk is considered a staple item in the diet of those groups for whom vitamin D intake is most critical--in particular, infants, children, and pregnant and lactating women (7). Vitamin D is stable in milk, and it can be added at small cost by feeding cows irradiated yeast or irradiating the milk itself. In the 1940's it was found to be simpler and equally effective to add a vitamin D concentrate to milk, and this has become the principal method of fortification. Today vitamin D is added to a wide range of milk products, including fluid milk of varying fat levels, evaporated milk, and nonfat dried milk (7).

The Selective Service draft in the early 1940's focused attention on the poor nutritional status of many young adults, whose failure to pass physical examinations was related in part to faulty diets (8). In response to this situation, President Franklin D. Roosevelt called a National Nutrition Conference for Defense in May 1941. The purpose of the conference was to encourage nutritionists and other health professionals to initiate unified programs that would improve the national nutritional status. During the

conference it was recommended that bread and flour be enriched. The Food and Drug Administration had previously developed standards for enrichment programs, and these standards helped provide background information for deliberations during the remainder of the conference. Later these standards helped in gaining support for enrichment programs (8) because the standards had already undergone extensive review by conference participants representing most of the major health-oriented organizations. Voluntary cooperation of the baking and milling industries was so extensive that by the middle of 1942 three-quarters of the white bread baked in the United States was enriched with iron, thiamin, niacin, and riboflavin (8). War Food Order No. 1, issued in 1943, made mandatory the enrichment of white flour to be sold in interstate commerce. After the war ended, about half the States retained enrichment laws to take the place of the Federal order. Today, Federal regulations allow enrichment on a voluntary basis, but if a product is enriched, the levels of added nutrients must follow standards set by FDA for that product (6).

Food shortages which accompanied World War II led to widespread use of oleomargarine as a substitute for butter. When the war ended, many people continued using oleomargarine. FDA issued a final regulation in 1952 (revised in 1977) requiring that oleomargarine be fortified with not less than 15,000 International Units of vitamin A per pound as part of its standard of identity. That amount of vitamin A is roughly the level found in butter (6, 9).

FORTIFICATION TODAY

Extent of Coverage in the United States

From these early beginnings, fortification of foods has grown into a practice that is fairly common today in a wide variety of foods. A survey of enrichment and fortification practices covering the years 1966-70 showed that added nutrients supplemented the food supply in 1970 by the following percentages:

Nutrient	Percentages
Thiamin	40
Iron	25
Niacin	20
Riboflavin	15
Vitamin A value	10
Ascorbic acid	10
Vitamin B6	4
Vitamin B12	2

Foods which the survey found to have been supplemented included various cereal products, flour and baked goods, beverages, milk, infant formulas, margarine, and formulated meal replacements (10).

A survey conducted in 1969 to assess the nutritional status of 100 women during pregnancy (11) disclosed that 99 percent of the participants consumed some kind of fortified food as a part of their regular diet. Examination of these regular daily diets revealed that 97 percent contained foods fortified with iron, thiamin, riboflavin, and niacin; 75 percent contained foods fortified with vitamin A; 60 percent contained foods fortified with ascorbic acid; and 49 percent contained foods fortified with protein by the addition of milk solids to lowfat milk or soy protein to cereals.

Comparisons of the results of the 1965-66 and 1977-78 Household Food Consumption Surveys show an increase in consumption of some snack foods, such as soft drinks and dessert mixes (12). This increased consumption of snack foods has been associated with decreased intakes of some nutrients, and there has been a move to fortify some of these products (13). Doughnuts, pizza, formulated potato products, and a grain-fruit product, fortified to a percentage of the Recommended Dietary Allowances (RDA) with many nutrients,

are available at the retail level (14). Industry officials have stated that the fortification of snack foods is an attempt to let people eat the foods they wish and still assure that good nutrition has been provided (14). Industry marketing reports indicate that consumer response has been supportive (14).

Effects of Fortification on Health

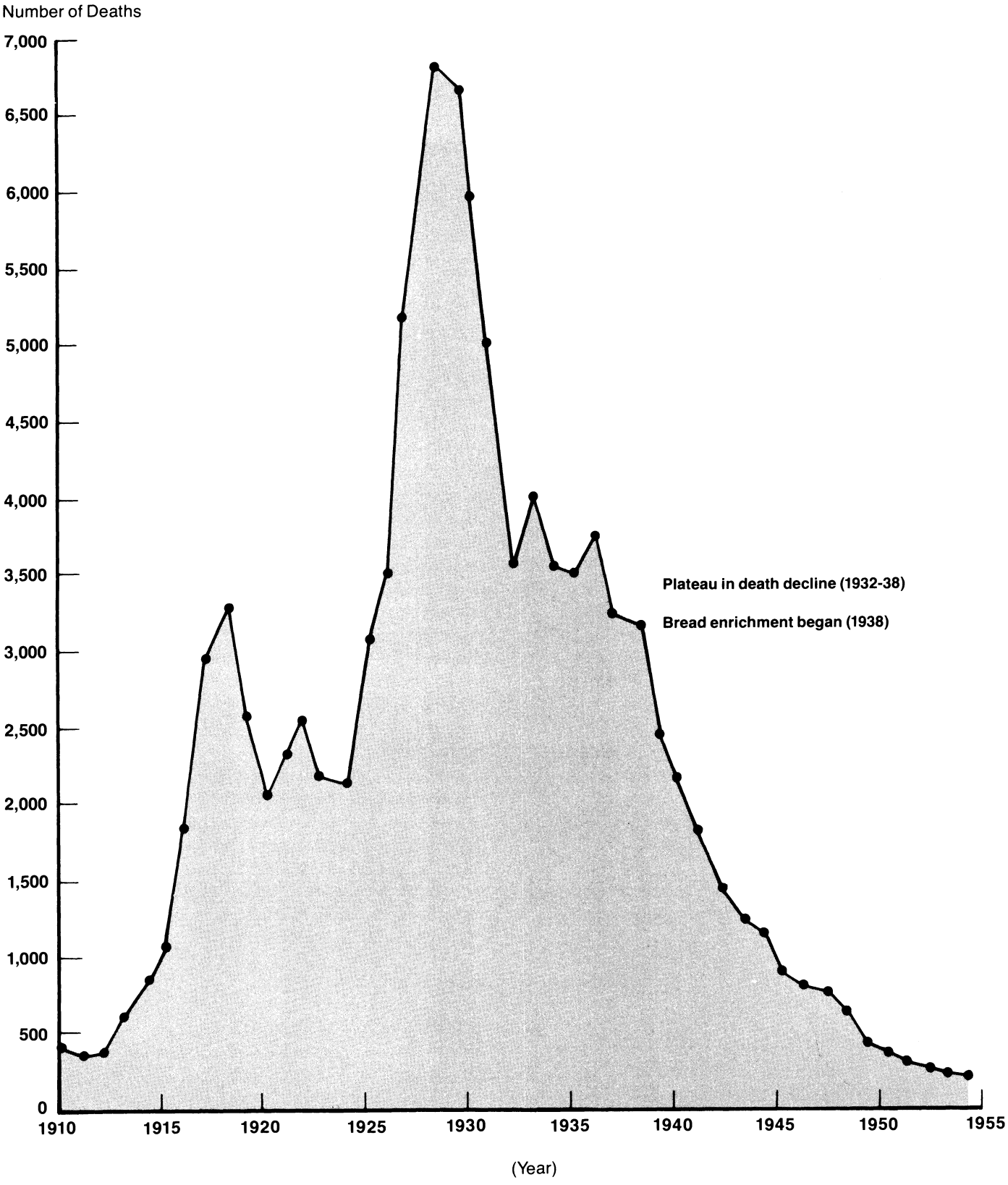
The effectiveness of fortification programs in eliminating deficiency diseases has been praised by many nutritionists (6,7,14). Certainly an improved standard of living since World War II has also had a beneficial effect on the American diet. Developments in processing and storage technologies, such as the development of frozen fruit juice concentrates, have also been beneficial. In various discussions of the relative effect on nutritional status of fortification programs as opposed to other factors, it has been unclear as to just how effective fortification alone would be (15). An improved economy, increased knowledge of nutrition, better storage technology, and other factors would all have potential for affecting nutritional status in the United States. Although both fortification and an improved standard of living have been beneficial, in the case of pellagra there is some evidence that fortification of breads with niacin decreased the incidence of this disease over and above the effect of an improving economy. Figure 1 shows the number of deaths due to pellagra from 1910 to 1955. The decrease in the number of deaths from 1918 to 1925 could possibly have resulted from the booming economy of this period. The graph shows a growing death toll from this disease until the late 1920's, when pellagra was identified as a disease of niacin deficiency. A steep decline in deaths began at about the same time as the great depression began. Deaths from pellagra leveled off during the period from 1932 to 1938 while the economy was starting to improve. The next obvious change is the sharp decrease in deaths following 1938, when bread enrichment programs began. Subsequent dips in the graph correspond with later additions of more foods to enrichment programs (15).

Evidence of a response to food fortification has also been examined in clinical studies (15, 16). Data obtained in a field study with 384 5-year-old children from a Headstart program in New Orleans, La., showed improved serum folacin, serum iron, and transferrin saturation levels among children from low-income families receiving a beverage fortified with vitamins A, B2, B6, C, folic acid, calcium, phosphorus, iron, lysine, and tryptophan (16). Another aspect of this study showed that consumption of a highly fortified ready-to-eat breakfast cereal resulted in greatly increased serum vitamin A levels in these same children (16). The children participating in the study had low initial serum levels for vitamin A and iron. In a field experiment of this kind, it is very difficult to attribute serum response solely to fortification since all other variables are not controlled.

In a 1977 study involving elderly people in Boston, the effect of iron fortification on the mildly anemic was examined. Two-thirds of the 221 participants were given iron-fortified grain products daily for 6 to 8 months. The rest of the participants received the same foods without the added iron. Both groups experienced a marked increase in hemoglobin levels that the authors could not attribute to fortification but rather to an undefined intervention effect (17).

Evidence of clinical response to food fortification continues to be inconclusive, and a direct relationship between food fortification and improved nutritional status is difficult to establish. Some of the factors involved in evaluating fortification programs

Figure 1. Deaths from pellagra in the United States, 1910-54.



Source: National Center for Health Statistics

will be discussed in more detail in later sections of this report. It is clear, however, that food fortification is still considered by many nutritionists to have been, and to continue to be, an important factor in dealing with deficiency diseases and nutritional problems in the United States (6,7,8, 15).

The lack of abundance of some nutrients, such as iron, in foods, increasing numbers of teenage pregnancies, decreased food energy intakes, and special nutritional problems caused by the use of oral contraceptive agents have made it increasingly difficult for some girls and young women to obtain a nutritionally adequate diet from conventional foods. Clinical signs suggesting specific nutrient deficiencies in children and women of child-bearing age were discovered in the 1971-74 Health and Nutrition Examination Survey (HANES), but the percentages of people affected were very small (18).

Further information uncovered by the HANES on consumption patterns showed mean dietary intakes of some nutrients, particularly iron, to be low for many, when compared to the Recommended Dietary Allowances (RDA) (19). Approximately 95 percent of children aged 1-3 years and of females aged 10-54 years had iron intakes below the 1968 RDA. Mean iron intakes for these age groups ranged from 40-56 percent below the standard. Mean hemoglobin levels ranged from 11.9 to 12.6 for children aged 1-3 years and from 13.6 to 14.0 for females aged 10-54 years (20). The HANES also showed low intakes of vitamin A, calcium and vitamin C, but mean intakes for these nutrients did not fall as far below the standard as did iron (19).

Preliminary reports from the USDA Nationwide Food Consumption Survey of 1977-78 indicate decreased intakes of calcium, vitamin A, and riboflavin for some groups in comparison to data on individuals in the 1965 Household Food Consumption Survey (3). Henderson has indicated that low levels of intakes are considered to result from improper food selection rather than from a lack of availability of nutritious foods (13). Intakes of essential nutrients below the recommended allowance do not indicate the presence of a deficiency within an individual. Instead, low nutrient intakes can be used as an indicator of dietary trends and as a method of predicting the possibility that deficiency disease could occur.

State Policies on Food Fortification

In 1977, comparisons were drawn between State fortification laws and Federal policies for cereal product enrichment (19). Although Federal regulations establish standards for enrichment of some cereal and grain products, these standards are for the amounts of nutrients to be added, but do not determine whether nutrients must be added to which products. Individual States have addressed this question of mandatory fortification of cereal products. As of October 1977, 35 States and Puerto Rico had cereal enrichment laws in effect. Except for Utah, all of these States require certain staple cereals to be enriched to meet Federal standards when those products are enriched. Most State laws allow for automatic adoption of new Federal standards whenever changes occur. In those States where adoption is not automatic, a time lag occurs until state laws can be updated. This lag can cause considerable difficulties for cereal manufacturers and has led to a call for nationwide implementation of a model enrichment law (21).

As of October 1977 the following States and territories did not require cereal enrichment: Delaware, District of Columbia, Guam, Illinois, Iowa, Maryland, Michigan, Minnesota, Missouri, Nevada, North Carolina, Pennsylvania, Tennessee, Utah, Vermont, Virgin Islands, Virginia, and Wisconsin (21). At that time North Carolina was expected

to reinstate mandatory cereal enrichment laws that were more comprehensive and enforceable than the previous enrichment laws of that State. Mandatory laws have been considered by Michigan, Wisconsin, and Guam (21).

A USDA report on Federal and State standards for the composition of milk products, released in 1981, contains information on the addition of vitamins A and D to milk products (22). Table 1 compares State and Federal policies on fortification of whole milk, lowfat milk, and skim milk, as reported by USDA. As is evident from the table, most States follow Federal guidelines, either by stipulating the addition of vitamins A and D in specific quantities which match current Federal standards or by simply declaring that Federal standards will be followed. However, many States do not address the question of whether or not to fortify lowfat milk at any level.

Food Fortification Needs and Practices in Other Countries

Among the serious international nutrient deficiency diseases is protein-calorie malnutrition (PCM) (23). PCM is usually found in densely populated, technologically less developed nations, where the most efficient production of food is achieved by cultivating cereal grains and starchy roots and fruits (24). This practice helps alleviate the immediate need for calories (which are often deficient) but leaves little room for adequate production of leguminous seeds or animal protein products.

Even if enough food can be produced to supply ample calories, protein quality and quantity are often so poor that malnutrition may result. Coupled with inadequate supplies of foods is the difficulty of preserving foods (24). When protein and calorie intakes are increased, PCM is frequently found to have masked other nutrient deficiencies. In one case, the use of dried skim milk as a protein supplement touched off vitamin A deficiencies. The use of unfortified milk resulted in decreased consumption of standard vitamin A sources in some developing countries and was credited with increased incidence of xerophthalmia (a disease of the eye caused by vitamin A deficiency). This disease is characterized by impaired vision, and in severe cases, permanent blindness (25). The Food and Agriculture Organization of the United Nations and the United States maintain the policy that skim milk supplied to developing countries should be fortified with vitamin A.

India: In 1969 a seminar was held by the Indian Association of Food Technologists to discuss protein fortification of foods (26). The participants discussed the problems of PCM as well as current developments in protein fortification technology. The use of cottonseed protein flour, soy protein, and single cell protein as additional protein sources was outlined, as was the use of these products after fortification with amino acids. Concluding remarks from the seminar made no recommendations concerning food fortification, but did summarize points that had been made repeatedly throughout the papers presented. The nine points considered most important by the food technologists when discussing protein fortification of foods were (26):

1. The food in which the fortifying ingredient is used should be be consumed by a sizable portion of the population.
2. Fortification ingredients should be sufficiently inexpensive to permit consumption by the low-income groups in greatest need of these nutrients.
3. It is necessary to be able to process the ingredient or nutrient centrally in units large enough in size and few engough in numbers to maintain careful control.

Table 1--State, territorial, and federally regulated levels for addition of vitamins A and D to milk (USP units/quart)

ITEM	Vit. A in whole milk	Vit. A in lowfat milk	Vit. A in skim milk	Vit. D in whole milk	Vit. D in lowfat milk	Vit. D in skim milk
Federal	2,000 1/	2,000	2,000	400 1/	400 1/	400 1/
Alabama	—	2,000	2,000	400	400	400
Alaska	2/	2/	2/	2/	2/	2/
Arizona	3/	3/	4/	400	400	400
Arkansas	4/	—	1/	400	—	400
California	3/	—	3/	400	—	3/
Colorado	3/	—	5/	400	—	5/
Connecticut	2,000	2/	2,000 2/	400	2/	400 2/
Delaware	4/	—	4/	400	—	400
District of Columbia	illegal	—	2,000	400	—	400
Florida	2,000 2/	2,000 5/	2/	400 2/	400 5/	2/
Georgia	2,000	2,000	2,000 2/	400	—	400 2/
Hawaii	—	2/	2/	400	2/	2/
Idaho	2,000	—	6/	400	—	6/
Illinois	3/	—	2,000	400	—	400
Indiana	2/	2/	2/	2/	2/	2/
Iowa	3/	3/	3/	400	400	400
Kansas	2,000 5/	2,000	2,000	400	400 5/	400 5/
Kentucky	4,000	2,000 1/	2,000	400 1/	400 1/	400 1/
Louisiana	Illegal	2,000	2,000	400	400 1/	—
Maine	2,000 1/	—	2,000 5/	400	—	400 5/
Maryland	2,000	—	2,000	400	—	400
Massachusetts	2/	2/	2/	2/	2/	2/
Michigan	2,000 1/	2,000	2,000	400 1/	400 1/	400
Minnesota	2/	—	1/	400	—	400
Mississippi	illegal	—	2,000	400	—	400
Missouri	2,000 5/	2,000	2,000	400 1/	400 1/	400 1/
Montana	2/	—	2/	400	—	400 2/

continued

See footnotes at end of table.

Table 1--State, territorial, and federally regulated levels for addition of vitamins A and D to milk (USP units/quart)--continued

ITEM	Vit. A in whole milk	Vit. A in lowfat milk	Vit. A in skim milk	Vit. D in whole milk	Vit. D in lowfat milk	Vit. D in skim milk
Nebraska	2,000	___	2,000 2/	400	___	400
Nevada	___	2,000	2,000	400	___	400
New Hampshire	2/	2/	2,000	400	2/	400
New Jersey	2,000	___	3/	400	___	400
New Mexico	3/ 4/	___	3/	400	___	400
New York	2,000 1/	2,000	2,000 1/	400 1/	400 1/	400 1/
North Carolina	3/	5/	2,000	400	5/	400
North Dakota	2,000	___	2,000	400	___	400
Ohio	3/	2,000	2,000	400	400 1/	400
Oklahoma	2,000	___	___	400	___	400
Oregon	2,000 2/	2,000 2/	2,000 2/	400 2/	400 2/	400 2/
Pennsylvania	2,000	1/	2,000	400	1/	400
Puerto Rico	3/	2/	3/	400	2/	400
Rhode Island	4,000	___	2,000	400	___	400
South Carolina	3/	___	2,000	400	___	400
South Dakota	5/	___	___	400	___	400
Tennessee	5/	___	2,000	400	400 1/	400
Texas	4/	___	2,000	400	___	400
Utah	___	___	2,000	400	___	400
Vermont	2,000 1/	2,000 1/	2,000 1/	400 1/	400 1/	400 1/
Virginia	4/	___	2,000	400	___	400
Washington	3/ 4/	5,000	3/	400	___	400
West Virginia	4,000	___	2,000	400	___	400
Wisconsin	2,000	___	2,000	400	___	400
Wyoming	2,000	___	2,000	400	___	400

1/ Optional, but when added, not less than quantity shown.
2/ Follows FDA standards.
3/ Quantity not stipulated, but must be declared on the label.
4/ Quantity to be approved by state regulatory authority.
5/ Optional.
6/ Follow U.S. Public Health Service definition.

4. The ultimate food in which the ingredient is used should lend itself to a distribution mechanism capable of covering large geographic areas.
5. The fortified ingredient must not affect taste, odor, or appearance, and therefore be fully acceptable to the consumer.
6. It must permit further processing or cooking without losses.
7. It must be consumed in relatively constant amounts (so that levels can be accurately calculated).
8. The ingredient or food must be fortified without causing significant increases in costs to users.
9. There is an attractive spectrum of ingredient possibilities available to the policymaker and the scientist interested in fortifying foods. Choices include proteins of high biological value that are low in cost and in plentiful supply.

Panels of food industries and the Ministry of Commerce and Industry in India have made recommendations for vitamin fortification of various foods (26 27). In 1953 atta, a type of whole wheat flour, was fortified with calcium carbonate, and white flour with B vitamins and calcium carbonate, using standards from other countries for guidance. The panels also recommended that vanospati, a hydrogenated vegetable fat, be fortified with vitamin A to the level of 700 international units per ounce and that rice, breakfast foods, and fruit juice be fortified. Iodization of salt was recommended (26), as well as fortification of salt with iron and calcium (28). Several fortified food products have been developed under the auspices of the Indian Council of Medical Research for use as weaning foods for infants and snack foods for preschool children (29). These products are based on inexpensive local foods, and tests have shown them to be acceptable to children and effective in improving their diets, as indicated by increases in body heights and weights.

Canada: Fortification of bread flour with niacin, thiamin, and riboflavin and of margarine with vitamins A and D began in Newfoundland. Fortification began following a survey in a small fishing village of that province which showed "widespread inadequacies and deficiencies" for these nutrients (26). Surveys conducted after fortification showed a sharp decline in the death rate that was accompanied by or attributed to decreases in such diseases as tuberculosis. Because this disease is not nutrition related the decline indicates an overall improvement in health and resistance to illness (26). Voluntary fortification of white flour throughout the rest of Canada began in 1952 with a standard that included the addition of milk powder to a level of 2 percent by weight (26).

Great Britain: Shortages in Great Britain during World War II caused growing concern over the quality of the British diet, which up to that time had relied heavily on imported food products. Prior to the War bread flour was prepared by a 72-percent extraction procedure--that is, the milled flour contains 72 percent of the unprocessed wheat kernel, leaving 28 percent bran, germ, and other byproducts to be used as animal feed. In 1940 it became apparent that nutritional deficiencies might arise with continued use of the 72 percent flour, so in 1942 the extraction percentage was raised to 82. This resulted in a product with acceptable organoleptic qualities. Later, the extraction rate was raised to 85 percent, resulting in a product that was resisted by the civilian population (26). It seemed that the British people

equated the whiteness of bread with cleanliness and wholesomeness, and the darker bread was considered highly questionable (26). The British Government launched a promotional campaign and people grudgingly began to accept bread made with flour having extraction levels up to 90 percent as an unavoidable burden of war. In the period from 1945 to 1950, the extraction level of flour was kept high at the Government's request in order to reduce strain on the British budget, but people complained about the brown flour. The Government instituted a voluntary policy that the extraction level should be high enough to provide 0.24 mg thiamin, 1.6 mg riboflavin, and 1.65 mg iron per 100 g flour (26). Thus, improved nutritive value would be provided by the level of extraction and not by the addition of nutrients.

The baking and milling industries were successful, however, in convincing the Government to accept the principle of enrichment in view of the public's demand for white bread. Gradually the millers decreased the extraction level to 70 percent and lower, while adding synthetic nutrients to provide the amounts set forth in the governmental policy. Later, when calcium carbonate was added to flour, the presence of this compound had to be indicated in the ingredients statement by the Latin name "Creta Praeparta" to keep people from thinking lime had been added solely as a bleaching agent and that the high extraction flour was being used again without the public's knowledge (26).

Sweden: Fortification of foods with iron has been practiced for over 30 years. The average daily intake of this mineral in Sweden is 19 mg, 42 percent of which is supplied by fortified foods (30).

The Philippines: A study showing the beneficial effects of adding thiamin to rice was conducted on the Bataan peninsula in the Philippines during 1947-50. Deaths from beriberi in a severely deficient population of 63,000 were reduced from 167 in the first year to 49 deaths by 1949-50. The authors attributed this rapid decline in deaths to fortification more than any other factor (31). Rice in the Philippines is now fortified.

Japan: Japan began investigations on amino acid fortification in 1955. In April 1964, a Small Committee on Fortification with Amino Acids sponsored a nationwide study of lysine fortification of bread served in school lunch programs. There was no difference in growth between children in urban areas consuming the fortified bread and their counterparts consuming the unfortified bread. However, children in rural areas, who depended on rice and barley for their staple foods, showed increased growth, over controls, for the group receiving lysine-fortified bread. This finding led researchers to deduce that lysine was the limiting amino acid in rice and barley (32). Standards provided by Japan's Nutrition Improvement Law permit the addition of lysine to breads, noodles, biscuits, and other wheat flour products. These fortified products have been commercially available since 1962 (33), and are considered special dietary foods. Rice fortified with thiamin and riboflavin is sold commercially, but efforts to fortify this grain with lysine have been unsuccessful because the fortified product undergoes undesirable organoleptic changes. Also available in Japan is a simulated rice product, which is formulated from starches and proteins and can be fortified with any combination of vitamins and minerals, then coated with an edible film (33). This product has the advantage of being practical for any cooking method. It can be formulated in several ways to suit specific needs, and it can be made to closely resemble conventional rice.

Latin America: Several Latin American countries have experimented with fortification programs. Brazil and

Chile have conducted studies using sugar as a vehicle for vitamin A fortification (34, 35). Guatemala has been the site of studies by the Institute of Nutrition of Central America and Panama (INCAP) on corn supplemented with lysine, thiamin, riboflavin, niacin, vitamin A, and iron. Problems of consumer acceptance, increased bacterial spoilage, and higher costs for fortified products have prevented corn from being accepted as a carrier vehicle (36). In Guatemala, wheat flour is fortified by law with thiamin, riboflavin, niacin, iron, and calcium, with the added cost of fortification paid for by private industry (37). Legislation requiring iodization of salt was passed in Guatemala in 1954 (37).

Mexico's compulsory enrichment ranges in wheat flour for thiamin, niacin, riboflavin, and iron are similar to ranges used in the United States, except that maximum permissible levels are much higher. Wheat flour is also enriched with calcium to a specified range and salt is iodized (see Tables 2 and 3) (37). Mexico has considered requiring that fish protein concentrate (FPC) be added to all wheat and corn milled in communities over a certain size, so that fortified flour would reach over 90 percent of the population (23). Studies using products made with FPC-fortified flour have shown that consumers are either unable to detect any difference between fortified and unfortified products, or if a difference were noticeable, that the fortified products were considered acceptable (23).

Tunisia: Tunisia was the site of a wheat flour fortification study started in 1969 by the Harvard School of Public Health and Nutrition. The authors considered the program to be a qualified success. At Government-controlled mills flour was fortified with a vitamin-mineral premix containing thiamin, riboflavin, niacin, vitamins A and D, iron and calcium, with and without lysine. The fortified product was highly acceptable to consumers, but the unexpected existence of nongovernment-controlled mills made it difficult to determine whether or not adequate amounts of grain were being fortified (36). No effects of fortification were found when serum or urine of subjects in this study were examined for any of the added nutrients.

Thailand: Harvard researchers conducted a similar study in Thailand, utilizing synthetic granules closely resembling rice. Organoleptic qualities were a problem, but the people seemed willing to tolerate the product if it could be shown to improve the nutritional status of their children. The results of this investigation also indicated no response to fortification, but the authors postulated that a response might have been seen had the subjects been able to consume the fortified foods in amounts closer to caloric requirements (36, 38).

Many children attending preschool centers in Thailand are served foods fortified with textured vegetable protein (TVP) in lunch programs. Some centers also distribute protein-fortified cookies as snack foods. Consumer acceptance of these products has been so favorable that a fortified infant food has been developed. This weaning food can be held up to 8 months at room temperature without losing acceptability in quality characteristics (39).

Iran: Protein-fortified cookies have been used to supplement the Iranian School Lunch Program with a high degree of acceptability (40). The fortified cookies came in four varieties--brownie, oatmeal, toffee, and filled--which could be formulated to meet local or regional nutrient needs. This practice was in effect through August 1977, but political conditions in that country have made it impossible for a U.S. firm to continue to supply the cookies.

Egypt: Egyptian bread and two popular legume foods (lentil soup and falafil, a

TABLE 2--Salt iodization: Legislation on iodine fortification

Country	Level of iodine compound in salt	Date of legislation
Argentina	1:30,000 KI or iodate	1967 (goitrous areas only)
Bolivia	1:20,000 K iodate	1968
Brazil	1:50,000 to 100,000 K iodate	1953 (goitrous areas only)
Canada	1:10,000 KI or NaI	1949
Chile	1:10,000 KI or iodate	1959
Colombia	1:10,000 to 20,000 K iodate	1955
Costa Rica	1:36,000 K iodate	1961
Ecuador	1:20,000 K iodate	1968
El Salvador	1:15,000 K iodate	1967
Guatemala	1:10,000 to 15,000 K iodate	1954
Honduras	1:15,000 K iodate	1968
Mexico	1:66,000 KI or NaI	1962(goitrous areas only)
Nicaragua		
Panama	1:10,000 to 15,000 K iodate	1955
Paraguay	1:10,000 K iodate	1954
Peru	1:10,000 KI	1940 (goitrous areas only)
United States	1:10,000 KI	
Uruguay	1:30,000 KI or iodate	1963
Venezuela	1:500,000 K iodate	1966

Source: Chopra, J.G., 1974 (37).

Table 3--Fortification of cereal grain products with vitamins and minerals, by country

Country/item	Thiamin	Riboflavin	Niacin	Iron	Calcium
		milligrams/kilogram			
Canada					
wheat flour 1/2/	4.4-5.5	2.65-3.3	35-44	28.7-36.4	1.1-1.4
Chile					
wheat flour & rice 1/3/	6.3	1.3	13	13.3	1.7
Costa Rica					
wheat flour 2/3/	4.4-5.5	2.6-3.3	35.2-44	28-36.4	1.1-1.38
Dominican Republic					
wheat flour 3/	4.4-5.5	2.6-3.3	35-44	28-36.4	1.1-1.38
El Salvador					
items not specified 3/4/	Yes	Yes	Yes	Yes	Yes
Guatemala					
wheat flour 3/5/	4.4	2.6	35.0	28.77	1.7
Honduras					
wheat flour 3/6/	Yes	Yes	Yes	Yes	Yes
Mexico					
wheat flour 3/	4.4-8.8	2.6-5.2	35-70	28.6-57.3	------
Nicaragua					
wheat flour 3/	4.4	2.6	35.0	28.7	1.1
Panama					
wheat flour 3/4/	4.4	2.6	35.2	28.7	1.1
Puerto Rico					
wheat flour 3/	4.4-5.5	2.6-3.3	35-44	28.7-36.4	------
rice 3/	4.4-8.8	2.6-5.3	35-70	28.7-57.3	1.1-2.2
United Kingdom					
rice flour 3/	2.4	------	16	16.5	------

continued

Table 3--Fortification of cereal grain products with vitamins and minerals, by country*-continued

Country/item	Thiamin	Riboflavin	Niacin	Iron	Calcium
	milligrams/kilogram				
U.S.A.					
wheat flour 2/3/	4.4-5.5	2.6.-3.3	35-44	28.7-36.4	_____
corn meals & grits 2/3/	4.4-6.6	2.6-4.0	35-53	28.7-57.3	1.1-1.7
rice 2/3/	4.4-8.8	2.6-5.3	35-70	28.7-57.3	1.1-2.2
pasta 2/3/	8.8-11.0	3.8-4.9	60-75	28.7-36.4	_____
Uruguay					
wheat flour 1/4/5/	Yes	Yes	Yes	Yes	Yes
Venezuela					
wheat flour 1/4/5/	Yes	Yes	Yes	Yes	Yes
Caribbean					
wheat flour 1/	4.4-5.5	2.6-3.3	35-46	28-36	1.1-1.4
West Indies					
wheat flour	4.5-5.5	2.6-3.3	35-46	28-36	1.1-1.4
Trinidad 3/	_____	_____	_____	_____	_____
Tobago 3/	_____	_____	_____	_____	_____

Source: Chopra, J.G., 1974 (37).

1/ Fortification not compulsory.
2/ Labeling compulsory if product is fortified.
3/ Fortification compulsory.
4/ Cost to consumer.
5/ Cost to proviate industry.
6/ At 80% cost to private industry and 20% to consumers.

*There is no fortification program in British Honduras, Bolivia, Columbia, Cuba, Ecuador, Haiti, Paraguay, and Surinam. Fortified imported flour is purchased by Antigua, Dominica, Grenada, Monserrat, St. Lucia, Nevis, St. Kitts, St. Vincent, Barbados, Guyana, and Jamaica.

fried cake of broad beans and seasoning) have been fortified in Egypt with full-fat and defatted soybeans in an effort to increase protein levels for these foods. An evaluation panel gave very high quality ratings for these foods and the authors expressed an optimistic outlook for consumer acceptance of these fortified products (41).

Tables 2, 3, and 4 provide an overview of policies in various countries for fortification of salt, cereal and grain products, and some dairy products. The lists show that a number, but not all, of the countries have compulsory programs.

South Africa: In 1976, the South African Medical Research Council assembled a group of experts to review research on food fortification in South Africa and other countries. The group was asked to evaluate practicality of the programs, efficacy, consumer acceptability, and economic implications. After looking over various programs, the group recommended immediate implementation of the following activities in South Africa:

1. The fortification of maize (corn) meal with riboflavin and nicotinic acid (niacin).
2. The fortification of maize meal with folic acid, provided the proposed fortification of maize meal with riboflavin and nicotinic acid were adopted.
3. The restoration of vitamin A content to skimmed milk by the addition of 1,500 international units per liter.
4. The fortification of all processed and evaporated milks with 400 international units of vitamin D per liter.
5. The fluoridation of water supplies in areas of low fluoride intake.

General recommendations were made that nutrition education training should be provided to physicians and also that implementation of any food fortification program should be accompanied by a comprehensive evaluation of the program's effectiveness (42).

TECHNOLOGICAL ASPECTS OF FOOD FORTIFICATION

Any discussion of food fortification is enhanced by considering the technology of preparing synthetic nutrients and adding them to foods. Problems of bioavailability, excessive or toxic intakes, compliance monitoring, and choice of carrier ingredient or food are among the factors which should be taken into account in evaluating current and future technologies.

Bioavailability of Nutrients

Recent research has provided knowledge on how some nutrients interact with each other and are affected by reactions in the body and by processing. Researchers continue to try to identify the factors determining why a given quantity of a nutrient can furnish widely varying amounts of bioavailable nutrient when added in different chemical and physical forms, when associated with various carrier foods, and when fed to different individuals. Iron has been the subject of considerable research on bioavailability factors and the amounts of influence each factor can have upon the total iron absorbed (43-49). The most biologically available form of iron is heme iron, or iron from hemoglobin or myoglobin in meats, poultry, and fish. Nonheme iron, from vegetable sources, is absorbed more slowly and less completely than heme iron (46). Certain foods consumed with the iron food source, notably foods containing ascorbic acid or meat, can improve the absorption of iron (43). Other factors such as the individual's need for iron, the digestibility of the iron source, food processing effects (such as heat-induced chemical changes), and the chemical form and particle size of the iron all influence

Table 4--Foods for which fortification is specifically regulated (other than cereals and salt)

Country	Product	Nutrient	Remarks
Barbados	Margarine	Vit. A 1000 IU/oz	66% fortified
Canada	Breakfast foods	Iron not less than 4 mg/portion	
Chile	Margarine	Vit. A 30 IU/gm	Permitted
Columbia	Margarine	Vit. A 30 IU/gm	
Costa Rica	Margarine	Vit. A 9000 IU/460 gm	
	Milk	Vit. A 5000 IU/liter Vit. C 35 mg/liter Vit. D 500 IU/liter	
Guyana	Margarine	Vit. D 100 IU/oz	
Jamaica	Margarine		
Peru	Evap. milk	Vit. D 400 IU/liter	
St. Kitts and Nevis	Margarine	80-100 IU/oz (imported from U.K.)	Margarine imported from Carifta countries should contain some Vit. A and D. No quantitative amounts specified
St. Vincent	Margarine	Vit. A 760-940 IU/oz	
Trinidad	Margarine		
Venezuela	Margarine	Vit. A and D	
West Indies	Margarine		

Source: Chopra, J.G., 1974 (37).

bioavailability (47). Curing of animal products may decrease the bioavailability of the heme iron these products contain (49).

Attempts have been made to rank iron supplements according to their bioavailability (48), and methods have been developed to calculate the available iron from a food source (46, 48). Both of these kinds of analyses would need to be utilized to predict the amount of bioavailable iron in a fortified food. Fortification with forms of iron that have low availability is of questionable value in solving problems of iron nutriture, and can serve to confuse consumers by making a product appear nutritionally superior to its actual worth.

Unfortunately, iron sources with low availability are sometimes the only forms which can be added to a specific product without adversely affecting organoleptic qualities (48). This problem is discussed in a later section of this report. The high chemical reactivity which makes a particular iron source available for easy intestinal absorption also makes the iron more reactive with other constituents of the food it fortifies, promoting changes in color, texture, and flavor (48).

Similar problems of bioavailability are found with some other nutrients. Bioavailability and stability of added folacin were important factors in explaining why the feeding of fortified breads to healthy adults resulted in smaller increments in serum folic acid levels than were obtained when aqueous solutions of folic acid were fed (50). The bioavailability of zinc in soy-fortified wheat bread fed to rats has been found to be influenced by a phytate-protein-zinc complexing effect (51). Other nutrients which appear to be variable in bioavailability include manganese, copper, magnesium (52), vitamin B6 (53), calcium, and phosphorus (54). Research reports on bioavailability factors are greatly increasing in number, so there is good reason to believe other nutrients may soon be added to this list.

Excessive Intakes, Imbalances, and Toxicity

Individual differences in absorption efficiency of some essential nutrients could lead to toxicity effects in some segments of the population if highly fortified products begin to comprise a large segment of diets. Recent evaluations of iron enrichment policies debate this very question. FDA published a proposal in 1971 and a proposed rule in 1973 to increase the standard of iron enrichment of bread and flour from 8.0-12.5 mg to 25 mg per pound for bread and from 13.0-16.5 mg to 40 mg per pound for flour (55). These actions led to numerous conferences, papers, and letters to editors of nutrition and medical journals from hematologists and medical experts, mostly objecting to the proposed increase. There was considerable debate among the scientific community at this time about the frequency of iron deficiency anemia, the effectiveness of fortification in controlling anemia, and the possible effect of increased iron levels on individuals suffering from hemochromatosis (44). Hemochromatosis, a disease in which the victim absorbs too much iron from food, has been known to be fatal (30). In African Bantu tribesmen, high daily intakes of iron from a popular beverage (Kaffir beer, which daily contributes an estimated 100 mg iron to the Bantu diet) have resulted in a high incidence of liver injury and liver cirrhosis (56).

In Sweden, a study monitoring iron stores in 96 percent of that country's population found that 5 percent of those studied had consistently elevated serum iron levels, and 2 percent showed preclinical signs of hemochromatosis. This incidence of the disease was higher than most authorities had previously thought (30). It has been estimated

that 42 percent of the iron intake in Sweden is supplied by fortification compared to an estimated 25 percent in the United States (30). Because of these findings and the concerns raised by hematologists and other experts, iron fortification standards were left unchanged by FDA (57).

Excessive intakes of nutrients could present problems in normal individuals if food fortification programs are not carefully administered. Research has shown that very high protein intakes can cause a negative calcium balance (58). Vitamins A and D have long been known to be toxic when consumed in large amounts (59). Hypervitaminosis A is characterized by loss of appetite, abnormal skin pigmentation, loss of hair, keratinization of skin, and pain and fragility in bones (60). Hypervitaminosis D results in hypercalcemia, anorexia, nausea, polyuria, and in very extreme cases, mental retardation (60). To date, incidence of hypervitaminosis has been primarily caused by ingestion of high potency vitamin supplements rather than food.

Various essential trace elements have been shown to be toxic when consumed in large quantities. Iron has already been discussed. Zinc, when consumed at levels above 2 g daily, produces acute gastrointestinal irritation and vomiting (59).

Iodine consumption, in concentrations used for disinfectant purposes, has long been known to be lethal, but food sources have always been considered safe. The Food and Nutrition Board, however, recommends that the many adventitious sources of iodine in the American food system, such as iodophors in the dairy industry, alginates, coloring dyes, and dough conditioners, be replaced wherever possible by compounds containing less or no iodine (59).

This recommendation presents a new aspect to consider when evaluating food fortification criteria. When examining the risk of nutrient toxicity, we must be aware of possible adventitious addition of that nutrient to a food. Minerals introduced into the food from machinery or direct or indirect additives, as well as obvious sources of the nutrient (such as the anticipated level of fortification and the amount naturally present in foods), should all be considered in setting safe levels of nutrient addition.

Other forms of nutrient intake may also become increasingly important. For example, manganese toxicity, affecting the central nervous system, has been observed in industrial workers who inhale manganese dust. It has not been observed as a result of food consumption (59). Nondietary forms of exposure, although limited to a select subgroup of the population, should be considered to prevent food fortification from touching off a toxic reaction or to provide proper education in the use of fortified foods by the select subgroup.

Fluoride consumed in excessive amounts before and during formation of the permanent teeth in children can cause mottling of the teeth (61). This discoloration of tooth enamel is unattractive but does not usually affect dental health. If fluoride consumption is further increased, a more serious deterioration of bone can result. Unlike tooth mottling, fluoride-related bone changes can develop at all ages. However, fluoride intakes would need to be greatly in excess of those allowing mottling of teeth and for an extended period of time for bone disease to develop (61). Toxicity from fluoride is not associated with food sources at this time, although water supplies high in fluoride are sometimes associated with mottling of teeth.

Selenium toxicity is sometimes a problem for livestock consuming accumulator plants grown in soil with a high selenium content (62). Toxicity

symptoms have not been observed in humans, but farm animals experience depressed growth, anorexia, emaciation, lack of vigor, stiffness of joints, loss of hair, cracked hooves, impairment of reproduction, anemia, and fatty liver. These symptoms occur when concentrations exceed 3 mcg selenium per gram of diet (59). The Food and Nutrition Board of the NRC suggests a maximum intake of 200 mcg per day for adult humans. Formulated foods, which are to be used for more than a month and to the exclusion of other foods, should furnish at least 50 mcg per day (59).

Excess intakes of molybdenum have been reported to cause symptoms similar to gout and to have an antagonistic effect on copper metabolism (59). High serum levels of this nutrient have been accompanied by high uric acid and xanthine oxidase levels and by excess urinary loss of copper (59).

For many of these trace minerals, requirements and toxic levels are not well defined. Levels of food consumption, individual nutrient needs, and factors affecting bioavailability can change the margins of safety. Thus it can be very difficult to determine safe and adequate fortification levels. Even though toxic reactions are usually associated with exposure to a nutrient from a supplement or other nonfood source, imprudent fortification practices could change this situation, especially for some subgroups of the population who may tend to consume a narrow range of foods in large quantities. Because of the possible dangers presented by imprudent fortification with some nutrients, it becomes especially important to accurately monitor the addition of nutrients.

Stability of Nutrients and Organoleptic Changes

The National Research Council of the National Academy of Sciences organized a workshop in 1974 for specialists to discuss the technological problems involved with food fortification. The published proceedings of the workshop indicate that discussion centered around the stability of nutrients and their resistance to destruction by processing techniques, and around the effects of added nutrients on organoleptic qualities of foods (63). Knowledge of changes in nutrient composition during storage or from processing is necessary to make reasonable estimates of finished product nutrient composition. Development of industry guidelines to assure that a final product meets targeted nutrient contents would be based on these estimates.

The mechanism for fortification must consider the specific food to be fortified and the specific nutrient or nutrients to be added. Before a plan for nutrient addition can be formulated, consideration must be given to several factors: 1) the various effects that processing of the food might have on the nutrient(s) to be added; 2) nutrients or ingredients already present in the food, or chemical properties of the food which could affect the nutrient(s) to be added; 3) the effect of the added nutrient on organoleptic qualities of the food and whether these effects might render the food unmarketable; 4) the effect of usual storage conditions on the fortified food; and 5) any effects on the added nutrient(s) from probable methods of preparation for consumption of the fortified food (63). After these possible effects are evaluated, the most acceptable form(s) of the nutrient(s) can be selected and an appropriate carrier food can be chosen.

Many of the deleterious effects from processing are easily recognized and can be altered. Also, the addition of the nutrient(s) can be scheduled at the end of the processing line after any washing, heating, or aerating procedures. For example, fortification of bread is easily accomplished by means

of a dry nutrient premix metered continuously into flour during milling or by dissolving the premix into the dough water (64). A food technologist attempting a more complicated procedure, the fortification of potato chips with fat soluble and water soluble vitamins, reported that the vitamins needed to be added as close to the end of processing as possible. In this case fortification was accomplished by premixing the vitamins with salt to be placed on the product just prior to packaging. Otherwise the normal processes of washing, peeling, slicing, and frying could have greatly diminished the final vitamin content (64). Obviously, a manufacturer understands the processing that is needed for a product, but sometimes information is unavailable on characteristics of the nutrients to be added and nutrient interactions with that product. Findings by rival manufacturers on processing effects are often kept secret (64). Fortification projects can be frustrating because scientific literature on processing effects does not always include the specific details a manufacturer requires such as kinetics data, specifics on blanching, pH values of the foods, and descriptions of market forms of the nutrients (64).

Constituents of the food and the food's chemical properties are also important considerations when designing a fortification program. Phytates naturally present in the food can bind to minerals that are added, copper can chemically alter vitamin C, vitamins A and D are unstable in acidic foods, while vitamin C and thiamin are unstable at a neutral pH. In processing sterile liquid products containing protein, such as canned meal replacements, minerals must be added very slowly and in sufficiently low concentrations or localized protein precipitation may occur and cause a grainy or settling defect in the product. This defect may not occur when the fortification procedure is being developed in the laboratory, and might show up only after commercial production begins (48).

Some of the reactions produced when nutrients, especially minerals, are added to foods result in undesirable organoleptic changes. Soluble iron salts, when added in amounts greater than 10 percent of the RDA, have produced an astringent aftertaste or chalkiness in fortified frozen dessert products (48). Color changes are a frequent problem when minerals are added to liquid dietary products. The addition of insoluble calcium or magnesium salts to these products results in a lighter color than would be expected. When soluble salts are used, a darker-than-expected color results (48).

Conventional periods of storage can also have important effects on added nutrients. Less bioavailable ferric orthophosphate has been added to liquid canned weight-control meals because it is superior to ferrous iron forms in the resulting flavor and appearance of the fortified product. It was found that a 2 to 5-month storage period was sufficient for most of the ferric iron to be dissolved and reduced to ferrous iron (48). Since this amount of time would be expected to elapse between processing and consumption under normal conditions, it makes sense nutritionally and technologically to use the form that is initially poorer in bioavailability for fortification of this product.

The stability of vitamins during storage can be enhanced by the use of dry vitamin premixes or by vitamin solutions which are sprayed on the product after processing is completed. Properties of the food, as previously discussed, continue to affect vitamin stability throughout the storage period. Fortification with vitamins is usually handled by adding a sufficient overage to assure that nutrition labeling claims

are in compliance for the expected shelf life of the product (64).

Even the best systems of fortification can be impaired if inappropriate methods of preparation are practiced by the consumer. As a final consideration in designing a fortification system, current preparation practices for the food to be fortified should be investigated. For instance, it does little good to coat rice or pasta with a vitamin mixture that will dissolve during rinsing if the consumer is likely to wash the product before consumption. Preformed vitamin A, which is unstable in an acidic environment, should not be used to fortify a food if the consumer is likely to add large quantities of vinegar or lemon juice as part of preparation. Ordinarily, such problems can be easily avoided, but regional and ethnic food preparation practices are not always well known. All of these various technical effects can interact to alter actual nutrient composition from what is originally intended.

STATEMENTS ON FORTIFICATION CRITERIA

As food fortification has become more prevalent and studies have been conducted to evaluate factors affecting fortification, various health professionals and policymaking groups have issued statements regarding the criteria which should be utilized in a food fortification program. Many of these statements were made in response to proposed rules or guidelines on fortification that had been developed by the FDA.

As previously described, the Food and Drug Administration has established standards of identity for enriched flours, cereals, and baked products defining "enriched" products in terms of the nutrients to be added and the quantities of addition. Standards also exist for the addition of vitamins A and D to milk products and the addition of vitamin A to oleomargarine. FDA had no published official policy concerning the addition of nutrients to foods in general until publication of a proposed rule in 1974 outlining principles the agency believed were right and proper for fortification practices (4). The proposed rule discussed criteria for three situations in which food fortification was deemed acceptable:

1) to correct or prevent a widespread nutrient deficiency that is recognized to exist or is predicted by the scientific community;

2) to balance the total nutritional profile to the caloric content of a food, especially for formulated or substitute foods; and

3) to restore nutrients lost in processing to levels inherently contained in the food.

FDA also proposed that any product to which nutrients were added, not in accordance with these policies, must bear a statement declaring that addition of nutrients "at the level contained in this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food." The listed exceptions to this proposal included infant formulas, foods for special dietary use, iodized salt, and foods for which there exist standards of identity or nutritional quality guidelines (4). 2/

FDA concerns with food fortification policies were shared by FSIS and the Bureau of Consumer Protection of the

2/ A nutritional quality guideline sets forth a nutrient composition, or range of nutrient composition, considered by the Federal Government to be appropriate for a given class of food. Nutritional quality guidelines are established by regulation from Federal agencies.

Federal Trade Commission in a publication of the agencies' tentative positions published in 1979. The agencies indicated their belief that consumption of substitutes for traditional foods would be likely to increase and that it was the agencies' responsibility to ensure that these foods were properly fortified. The agencies stated that although some nutrients, such as sodium and phosphorus, are over consumed, excessive consumption is usually a result of personal eating habits and not fortification. However, if the current restraint on fortification, (as exercised by the food industry) were to change, there would be cause for serious concern on the part of the agencies. Because of this possibility FDA announced its intention to publish fortification guidelines that food manufacturers would be encouraged to follow (65).

The FDA guidelines were published in January 1980 as a policy statement to promote the rational fortification of food and to preserve the balance of nutrients consumed in the American diet. The FDA made it clear that widespread fortification would not be encouraged, and the published guidelines should be followed to nutritionally improve foods by fortification. The guidelines were designed to cover most types of food, with the notable exceptions of fresh fish, meats, poultry, and produce (foods that are highly nutritious without fortification), as well as sugars, candies, carbonated beverages, and other snack foods (foods considered inappropriate for fortification) (5).

The guidelines listed three main situations in which fortification of foods was deemed appropriate. Fortification of food is desirable to correct a dietary insufficiency recognized by the scientific community to exist and known to result in a deficiency disease. In order to identify the dietary insufficiency, adequate information must be available to pinpoint the specific nutritional problem and affected population groups. In addition, a suitable carrier food for the nutrient(s) to be added must be selected. Suitable carrier foods are generally inexpensive staple foods already consumed by the target population. The foods must not react with the added nutrient(s) in a way that would alter the biological value of the nutrient(s) (5).

Fortification of foods is also considered appropriate when nutrients are added to restore levels inherent in a food prior to conventional processing and storage. Only nutrients which are known to have been present in the food in quantities of at least 2 percent of the USRDA can be restored, and all nutrients contained at that level should be added. Restoration of nutrients lost from poor manufacturing practices or storage and handling procedures is not appropriate (5).

Nutrients may also be added to foods to balance protein, vitamins, and minerals to the caloric content of the food. The food to be fortified in this situation must contain at least 40 calories in a normal serving. This quantity of calories is 2 percent of the 2,000 calories standard set by FDA. (There is no USRDA for calories.) Added nutrients to balance calories in foods containing less than 40 calories per serving would be made in amounts too small to significantly improve the nutritional value of the food. All nutrients identified by FDA as candidates for addition should be added for the nutrient-to-calorie balance to be achieved. The Food and Drug Administration identified 22 nutrients as candidates for addition to foods: protein, vitamin A, vitamin C, thiamin, riboflavin, niacin, calcium, iron, vitamin D, vitamin E, vitamin B6, folic acid, vitamin B12, phosphorus, iodine, magnesium, zinc, copper, biotin, pantothenic acid, potassium, and manganese. Table 5 shows the levels of these nutrients which should be present in the fortified food for each 100

Table 5--FDA-recommended fortification levels based on a caloric standard

Nutrient	USRDA	Level of nutrients per 100 kcal
Protein (PER < casein), g	65	3.25 1/
Protein (PER > casein), g	45	2.25 1/
Vitamin A, IU	5000	250
Vitamin C, mg	60	3
Thiamin, mg	1.5	.075
Riboflavin, mg	1.7	.085
Niacin, mg	20	1.0
Calcium, g	1	.05
Iron, mg	18	.9
Vitamin D, IU	400	20 1/
Vitamin E, IU	30	1.5
Vitamin B_6, mg	2	.1
Folic acid, mg	.4	.02
Vitamin B_{12}, mcg	6	.3
Phosphorus, g	1	.05
Iodine, mcg	150	7.5 1/
Magnesium, mg	400	20
Zinc, mg	15	.75
Copper, mg	2	.1
Biotin, mg	.3	.015
Pantothenic acid, mg	10	.5
Potassium, g	2/	.125
Manganese, mg	2/	.2

1/ Optional.
2/ No USRDA has been established for these nutrients.

calories contained in the food. The FDA guidelines also allow nutrient addition to a food intended to replace a traditional food in the diet. The addition of nutrients to these substitute foods should be designed to prevent nutritional inferiority of the substitute food (5).

When a food is the subject of a Federal regulation which requires, prohibits, or stipulates specific levels of nutrient addition, the regulation supersedes the FDA guidelines on general fortification practices. The guidelines stressed that nutrients added to foods should be stable in the carrier food, physiologically available from the food, added at levels unlikely to produce a toxic reaction, and in compliance with Federal regulations governing the safety of food substances (5).

Many of FDA's criteria were developed from statements or policies that had been released by the Food and Nutrition Board (FNB) of the National Academy of Sciences and the Council on Foods and Nutrition of the American Medical Association (AMA). These two organizations issued a joint policy statement on food fortification in 1968 (66) and an updated policy in 1973 (67). The updated policy statement contained seven conditions that should be met when fortifying a food:

1. The nutrient(s) to be added must be below a desirable level in the diets of a significant number of people.

2. The food to which the nutrient is added is generally consumed by a significant segment of the population in need.

3. The amount of the nutrient added makes a significant contribution to the diet of the population in need.

4. The added nutrient is stable in the food under customary conditions of storage and use.

5. The added nutrient is physiologically available from the food.

6. There is a reasonable assurance that an excessive intake which could reach a toxic level will not occur.

7. Any additional cost incurred by fortification should be reasonable for the intended consumer.

The 1973 statement also endorsed the concept of "nutrient density." Nutrient density is an expression of nutrient content in terms of caloric value of a serving of food as related to a standard like the RDA's (67). This concept was also used by FDA, but the term "nutrient-to-calorie balance" was used instead of "nutrient density." The AMA-FNB statement urged the improvement of processing techniques rather than dependence on restorative addition of nutrients, and endorsed the continued development of new and improved foods that will assure an overall diet of superior nutritional quality, greater variety and acceptability, and economic advantage for the total population (67). The FNB and AMA have also endorsed the specific practices of 1) the enrichment of flour, bread, degerminated corn meal, corn grits, whole grain corn meal, white rice, and certain other cereal grain products with thiamin, riboflavin, niacin, and iron; 2) the addition of vitamin D to milk, fluid skim milk, and nonfat dry milk; 3) the addition of vitamin A to margarine, fluid skim milk, and nonfat dry milk; 4) the addition of iodine to table salt; and 5) the standardized addition of fluoride to water in areas where the water supply has a low fluoride content (67).

The U.S. Department of Agriculture has not issued a general policy statement concerning food fortification but USDA does follow certain principles in evaluating meat and poultry products and in the administration of feeding programs conducted by the Department. For the Women, Infants, and Children

(WIC) Program, the foods used are required to contain high levels of vitamin A, vitamin C, calcium, iron, and/or protein (68). To meet this requirement a "package" of milk or infant formula, cereal, eggs, and fruit or vegetable juices was developed containing 1) whole milk fortified with vitamin D, other milks fortified with vitamins A and D in accordance with FDA standards, or infant formula containing 10 mg of iron per liter and 20 kilocalories per ounce, 2) cereal providing 45 percent of the USRDA for iron for infants in a 1/2-ounce serving or 45 percent of the USRDA for iron for adults and children in a 1-ounce serving, and 3) juices containing 30 mg vitamin C per 100 g, either naturally or by fortification. No other fortification is required, but products for this program are purchased by the participants in retail food stores with purchase credits, so it is likely that some of the products purchased contain other added nutrients (69).

Foods purchased by USDA for the School Feeding and the Needy Families Programs can be fortified products only if FDA has a standard for the product, as for enriched bread and flour or fortified milk (69). The one exception to this policy is that dehydrated mashed potatoes, to which vitamins A and C have been added, is allowed.

A formulated grain fruit product was developed by industry for use in school feeding programs. The use of this product was allowed as an alternate to the bread/cereal and fruit/juice requirements for school breakfasts in the Federal Register notice of March 27, 1974 (70), but authorization for use was later removed on June 30, 1978 (71). Reasons given for the removal of authorization were 1) the lack of evidence indicating a need for this product, 2) the belief by USDA that a well-balanced diet of conventional foods is the preferred source of adequate nutrition, and 3) the difficulty children might have in distinguishing a fortified versus an unfortified product, and the possibility that this difficulty could result in poor eating habits.

An enriched macaroni product, fortified with protein, has been developed to replace 1 ounce of poultry, fish, or cheese in the school lunch when 1 ounce of the dry macaroni is mixed with one of these animal products (69). FDA published a standard for this product but a stay was placed on the effective date (72). This standard is still used by the Food and Nutrition Service (FNS) of USDA as a basis for evaluating compliance with the type A school lunch pattern (69).

A cheese alternate product has been formulated to contain protein, fat, calcium, phosphorus, iron, magnesium, zinc, vitamins A, B1, B2, B6, B12, niacin, and folic acid at levels normally provided by cheese. When this product is combined with cheese, it can replace up to one-half of the cheese that would normally be used for the meat or meat alternate required in the Type A school lunch (73). The nutrient content specifications for this product were developed by FNS in consultation with FDA (69), and were published in the Federal Register.

The Animal and Plant Health Inspection Service (APHIS), from which FSIS is descended in part, published an interim regulation in 1976 on the use of plant protein products combined with cured whole pieces of meat (74). The interim regulation stated that nonmeat protein products used in combination with cured meat must contain nutrients within the range prescribed below, except that levels of naturally occurring nutrients above the prescribed levels would be accepted (74):

Nutrient/g protein	Amount
vitamin A	13 to 20 IU
thiamin	0.02 to 0.03 mg
riboflavin	0.01 to 0.02 mg
niacin	0.30 to 0.45 mg
pantothenic acid	0.04 to 0.06 mg
vitamin B6	0.02 to 0.03 mg
vitamin B12	0.10 to 0.15 mg
iron	0.15 to 0.25 mg
magnesium	1.15 to 1.75 mg
zinc	0.50 to 0.75 mg
copper	24 to 36 mcg
potassium	17 to 25 mg

The regulation was issued in interim form because USDA wished its final regulation to be in harmony with FDA's as yet unpublished regulations for fortified vegetable protein products. Concern over the legality of using an interim regulation caused the regulation to be revoked 6 months after issuance (75), but the provisions outlined in the regulation are still considered reasonable by FSIS.

The FDA published a tentative final regulation on plant protein products in 1978 to become effective in July 1979 (76). Distinctions were drawn to differentiate flours from granules from isolates in the tentative final regulation, based on percent protein by weight, which was to be calculated on a moisture-free basis excluding added flavors, colors, or other added substances. If the percent protein, calculated in this manner, is less than 65 the product would be a flour; if the percent protein is at least 65 but less than 90, the product would be a granule or flour granule; if the percent protein is 90 or higher, the product would be isolated protein. Each term would include the protein source as part of the name of the product, i.e., soy flour granules, or isolated peanut protein (76).

Standards of identity require that vegetable protein products, formulated to be used as substitutes for meat, seafood, poultry, eggs, or cheeses, must contain nutrients in proportions similar to the nutrient content of the food they are intended to replace. Table 6 shows the nutrient contents per gram of protein required for these substitute foods. This tentative final regulation for vegetable protein products is being evaluated by FDA.

USDA has had a general policy of not allowing direct fortification of meat and poultry products for many years (77). This policy is based on the philosophy that the addition of nutrients should be reserved for those instances in which there is a demonstrated need, and that meat and poultry products are highly nutritious foods and, therefore, do not need to be fortified. However, FSIS does allow fortified ingredients such as enriched flour to be used in meat and poultry products if those ingredients are fortified according to a standard, and allows fortification of meat or poultry products to fulfill a standard of identity (77). For example, enriched flour could be used in a frozen entree containing meat or poultry, or milk solids can be used in a sausage to fulfill a standard of identity. These fortified ingredients are permissible, but direct fortification of a roast or steak is not permissible.

A White House Conference on Food, Nutrition and Health was held in Washington, D.C., in 1969. The final report of the assembled experts from industry, government, academia, and consumer organizations made several recommendations to further national goals of improved health and nutrition. The first recommendation of the panel for a national nutrition policy was the implementation of an immediate food fortification program to relieve malnutrition (78). In order to achieve this recommendation it was suggested that the Secretaries of Agriculture and Health, Education and Welfare (now Health and Human Services) should publish a list of important foods to be immediately fortified with appropriate

Table 6--Nutrient levels required in vegetable prtein products substituting for conventional foods

Nutrients (units per gram protein)	Sausages, luncheon meats, or bacon	Seafood, poultry, or meats 1/	Eggs	Cream cheeses	Cottage cheese	Other cheeses
Percent protein 2/	13	18	13	9	14	24
vitamin A (IU)	13	13	91	146	--	39
thiamin (mg)	.02	.02	.01	--	--	--
riboflavin (mg)	.01	.01	.04	.02	.01	.02
niacin (mg)	.3	.3	--	--	--	--
pantothenic acid (mg)	.04	.04	.22	--	.02	--
vitamin B_6 (mg)	.02	.02	.02	--	.01	--
vitamin B_{12} (mcg)	.1	.1	.15	--	.05	.05
folic acid (mcg)	--	--	--	--	1	--
vitamin E (IU)	--	--	.15	--	--	--
biotin (mcg)	--	--	1.7	--	--	--
iron (mg)	.15	.15	.19	--	--	--
magnesium (mg)	1.15	1.15	--	--	--	--
zinc (mg)	.5	.5	.22	--	.06	.24
copper (mcg)	24	24	14	--	--	--
potassium (mg)	17	17	10	--	6	--
calcium (mg)	--	--	4.3	9	4	28
phosphorus (mg)	--	--	--	--	--	19

1/ Not including bacon, sausage, or luncheon meats.
2/ By weight.

nutrients. The list should consider ethnic, social, cultural, and regional preferences. It was suggested that each product on the list be fortified to make the food as nutritionally complete as possible without altering consumer acceptability, and that the level of nutrient addition be based on the caloric content of the food. It was considered important that the full range of nutritional knowledge and technology be employed to further this goal, while keeping these fortified foods at the lowest possible cost (77).

The Panel on Food Manufacturing and Processing from the White House Conference made the following recommendations regarding food fortification (79):

1. Authorize the fortification of fluid milks with multivitamins and minerals.

2. Enrich all wheat and corn flour at the mill and study the potential for broadening enrichment standards.

3. Industry should voluntarily enrich all milled rice, and undertake studies to preserve fortification levels in consumer use.

4. Authorize the enrichment of grain flour proteins with amino acids.

5. The U.S. Department of Agriculture should authorize the addition of calcium to meat products.

6. FDA should permit the addition of fish protein concentrate to formulated foods.

7. FDA should authorize the addition of suitable vitamins to canned fruit and vegetable products.

8. FDA should authorize the nutritional enrichment of chocolate products.

9. Industry should undertake nutritional enrichment of suitable snack foods.

10. Government programs should be developed to promote fortified foods for the poor.

Many noted nutritionists have commented on the relative merits of using food fortification as a means of improving the national nutritional status. Dr. Mark Hegsted, while on the faculty of the Harvard School of Public Health and Nutrition, reviewed various fortification principles in 1976 and concluded, "Fortification of foods with nutrients is a logical tool for the control of malnutrition and undoubtedly fortification will increase in the future. The major and unresolved problem for the immediate future, considering our fragmentary knowledge of the nutritional needs of man, is to develop a rational policy that prevents over-reliance on fortification. Experience demonstrates that, depending upon the nutrient involved, fortification may not be as effective as anticipated and may not be without risk" (80). These risks include the marketing of "convenience foods" which resemble mixtures of conventional foods and may or may not be nutritionally equivalent to conventional foods. The use of these "convenience foods" will require the consumer to become more sophisticated in knowledge of nutrition in order to assure consumption of a well-balanced diet. Another risk concerns the safety of fortification with all essential nutrients and the potential for excessive intakes by some members of the population (80).

Dr. Walter Mertz, Director, Beltsville Human Nutrition Center of the U.S. Department of Agriculture, has called fortification of foods with essential micronutrients one of the great accomplishments of nutritional science (81). However, Dr. Mertz has qualified this statement by saying that fortification is only one solution to nutritional problems and that any effective program must be dynamic, utilizing new advances in nutritional

knowledge as soon as they become available (81). Five areas where he believes it is especially important to incorporate new knowledge are 1) human requirements and nutritional status, 2) biological availability of nutrients, 3) interactions among fortification nutrients, 4) interactions between fortification nutrients and the carrier food, and 5) selection of a suitable carrier food for fortification (81).

Dr. Elaine Monsen of the School of Home Economics at the University of Washington has extensively studied the bioavailability of iron. In 1971 she stressed the need for iron fortification in the United States (82), advocating a policy which would insure adequate intakes to vulnerable groups while being safe for the population in general. She suggested that maximum levels of fortification be established for a few foods and that no other foods be fortified, citing 50 mg of iron per day as a level which would be safe and adequate. Dr. Monsen also suggested that consideration be given to fortification programs using amino acids and vitamins (82).

Dr. Jean Mayer, of Tufts University, while endorsing the principle of fortification, has warned against the indiscriminate addition of nutrients to foods (83). He warned that a diet of highly processed fortified foods could reveal that we don't know all the essential nutrients at this time. Deficiencies might result from this kind of diet. Other dietary components such as fiber, which are not nutrients, still make useful contributions to health. Dr. Mayer also stated that decreased consumption of low nutrient-dense foods could eliminate the need for additional fortification practices (83).

A position paper by the Food Department of Hoffman-La Roche, a marketer of bulk vitamins, stresses that the American consumer has a right to obtain 100 percent of the USRDA for all essential nutrients while consuming the foods of choice (84). In order to accomplish this level of nutrient intake, Hoffman-La Roche endorses responsible food fortification, utilizing the latest technological advances.

Dr. Paul LaChance of Rutgers University has been an enthusiastic advocate of food fortification, endorsing a concept he calls "nutrification." Nutrification is the addition of nutrients for which RDA's exist in proportion to calories contributed by protein in a food (85). It is LaChance's opinion that this concept would allow for fortification of conventional foods while not permitting fortification of snacks or desserts, which he considers inappropriate for fortification (86). He does not suggest changing present policies of enrichment and fortification, such as iodization of salt and the addition of vitamin A to milk (85).

Disapproval has been voiced concerning fortification but these criticisms generally center around programs of indiscriminate fortification and warn against insufficient knowledge of nutritional requirements (87, 88). Caution is dictated by both proponents and opponents of food fortification programs (80-88).

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